IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF OKLAHOMA

KRISTIN DAWN WHITE and STEVEN KENT PHELPS, JR., individually and as co-administrators of the Estate of STEVEN KENT PHELPS, the Deceased,	)	
Plaintiffs,	)	
v.	)	Case No. CIV-12-402-D
MYLAN, INC.; MYLAN PHARMACEUTICALS, INC.; MYLAN TECHNOLOGIES, INC.; MYLAN LABORATORIES LIMITED.; MILAN BERET PHARMACEUTICALS, INC.; VAL LABORATORIES; DULL LABORATORIES; ALLCARE PHARMACY FLOWERS & GIFTS, INC.; WALGREENS CO.; and CVS CAREMARK CORPORATION,	)	
Defendants.	)	

O R D E R

Before the Court is Mylan's Motion to Dismiss Plaintiffs' Complaint Under Fed. R. Civ. P. 12(b)(6) [Doc. No. 8], filed by Mylan, Inc.; Mylan Pharmaceuticals, Inc.; Mylan Technologies, Inc.; Mylan Laboratories Limited; Mylan Bertek Pharmaceuticals, Inc., and UDL Laboratories[1] (collectively, "Mylan"). Plaintiffs have timely responded in opposition to the Motion. Mylan has replied and filed supplemental authority. The Motion is thus at issue.

[1] The last two defendants state they were incorrectly identified in the caption of Plaintiffs' pleading as "Milan Beret Pharmaceuticals, Inc." and "Dull Laboratories" or "VAL Laboratories."

Factual and Procedural Background

This case concerns the death on December 6, 2009, of Steven Kent Phelps, allegedly due to a defective pharmaceutical product and resulting drug toxicity. Plaintiffs are his children and the co-administrators of his estate. Mylan was involved in the manufacture and distribution of the Mylan Fentanyl Transdermal System (MFTS), which is a pain patch generally prescribed for chronic pain management and designed to deliver a steady dose of fentanyl, a potent opioid drug. The case was filed in Pottawatomie County, Oklahoma, but was removed to federal court based on diversity jurisdiction under 28 U.S.C. § 1332.[2] Mylan now seeks dismissal of the case for failure of Plaintiffs' petition to state a claim upon which relief can be granted.

Standard of Decision

"To survive a motion to dismiss [under Rule 12(b)(6)], a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see Robbins v. Oklahoma*, 519 F. 3d 1242, 1247 (10th Cir. 2008). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Determining whether a complaint states a plausible claim for relief is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *See id*. at 679. Thus, for example, "[a] simple negligence action based on an automobile accident may require little more than the allegation

[2] Plaintiffs' petition also names as defendants three pharmacies that allegedly provided prescription drugs to the decedent during December, 2009. The Court has previously determined that Plaintiffs have no claim against the pharmacies and that one of them, Allcare Pharmacy Flowers & Gifts, Inc., was fraudulently joined to defeat removal. These defendants are, therefore, disregarded.

that the defendant negligently struck the plaintiff with his car while crossing a particular highway on a specified date and time." *Robbins*, 519 F.3d at 1248. The question to be decided is "whether the complaint sufficiently alleges facts supporting all the elements necessary to establish an entitlement to relief under the legal theory proposed." *Lane v. Simon*, 495 F.3d 1182, 1186 (10th Cir. 2007) (internal quotation omitted).

In deciding a Rule 12(b)(6) motion, "the sufficiency of the complaint must rest on its contents alone," with limited exceptions:

> (1) documents that the complaint incorporates by reference, *see Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007); *Oxendine* [*v. Kaplan*], 241 F.3d [1272,] at 1275 [(10th Cir. 2001)] (documents attached as exhibits to the complaint); (2) "documents referred to in the complaint if the documents are central to the plaintiff's claim and the parties do not dispute the documents' authenticity," *Jacobsen v. Deseret Book Co.*, 287 F.3d 936, 941 (10th Cir. 2002); and (3) "matters of which a court may take judicial notice," *Tellabs, Inc.*, 551 U.S. at 322 . . . .

Gee v. Pacheco, 627 F.3d 1178, 1186 (10th Cir. 2010). Mylan has attached to its Motion two exhibits other than a copy of Plaintiffs' pleading. These documents appear to be copies of the prescribing information, labeling, and instructions for (1) Duragesic, a name-brand fentanyl transdermal system, and (2) MFTS, the alleged generic equivalent. *See* Mylan's Mot. Dism., Ex. 2 [Doc. No. 8-2] and Ex. 3 [Doc. No. 8-3]. These materials form the basis of a federal preemption argument under *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), discussed below. The exhibits, however, are explained only in a footnote to Mylan's brief, asking the Court to take judicial notice of "the sameness of the labels" of the name-brand and generic products under Fed. R. Evid. 201 "because 1) the Duragesic label – which the Mylan label must match – is available on the FDA's website, and 2) both labels were approved by the FDA." *See* Mylan's Mot. Dism. [Doc. No. 8] at 14, n.7. Mylan also asserts the MFTS label is necessarily incorporated into Plaintiffs' pleading

by reference. *Id*. at 14. Through incorporation and judicial notice, Mylan contends that these materials may properly be considered in a Rule 12(b)(6) ruling.

Plaintiffs' Allegations

Plaintiffs allege the decedent's death was caused by his use of MFTS. Plaintiffs claim the product was defective in design and manufacture, and that Mylan failed to provide adequate warnings concerning its product. Plaintiffs seek damages for the decedent's wrongful death, including his pain and suffering, medical and burial expenses, and their grief and loss of companionship. Plaintiffs identify their legal theories to be strict products liability and negligence, and they identify the following negligent acts: Mylan allegedly a) "failed to use ordinary care in designing, testing, and manufacturing [MFTS] so as to avoid the high risk to users of unreasonable, dangerous side-effects . . . ;" b) "failed to accompany [MFTS] with adequate warnings that would alert doctors, consumers, and other users to the potential adverse side effects . . . ;" c) "failed to conduct adequate pre-clinical testing and post-marketing surveillance;" d) "failed to warn Plaintiffs' decedent . . . about the possibility of becoming disabled;" e) "continued to promote the safety of [MFTS] . . . even after Defendants knew of the risk or [sic] injury or death;" and e) was "otherwise careless or negligent." *See* Petition [Doc. No. 1-1], ¶ 17. Plaintiffs also allege Mylan violated federal laws and regulations regarding labeling, post-marketing reports, and promotion of drugs for unlabeled uses.

Defendants' Motion

By the Motion, Mylan contends Plaintiffs' petition is insufficient to state a plausible claim of defective design, manufacture, or warning because the petition contains only conclusory allegations; it does not identify any particular defect in the product or warning. Mylan also contends

Plaintiffs' claim for failure to warn is preempted by federal law, which mandates the product labeling and information to be provided. Mylan relies on recent Supreme Court authority, *Mensing*, 131 S. Ct. at 2578, holding that state law claims against a generic drug manufacturer for failure to provide adequate warning labels are preempted by federal statutes and regulations mandating that safety labels for generic drugs must be the same as the corresponding brand-name drug labels.

Plaintiffs respond that, under a notice-pleading standard, their pleading adequately states claims of negligence and strict products liability based on allegations of design and manufacturing defects in MTSF and based on the lack of a warning on the package label about using MTSF in conjunction with other pain relief medications. As to federal preemption, Plaintiffs argue that the holding of *Mensing* is inapplicable to strict products liability claims, and that *Mensing* does not preclude failure-to-warn claims involving MFTS because it is a "delivery system" and not a drug. Finally, Plaintiffs assert that the Motion is procedurally improper because it is not supported by an affidavit. While this argument seems contrary to Rule 12(b)(6), the Court understands Plaintiffs' position to be that Mylan has failed adequately to support its request for judicial notice of adjudicative facts under Fed. R. Evid. 201, because no FDA materials or proof of FDA approval is presented.[3]

Discussion

Upon examination of Plaintiffs' pleading under the federal standard required by *Twombly* and *Iqbal*, the Court agrees with Mylan that the petition lacks sufficient factual allegations to state a plausible claim of strict liability or negligence. As to strict products liability, the petition alleges

[3] Rule 201 permits judicial notice when a fact "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned" and mandates judicial notice "if a party requests it and the court is supplied with the necessary information." *See* Fed. R. Evid. 201(b)(2), (c)(2).

only that MTFS was defective; it does not provide any supporting factual allegations that would be "entitled to the assumption of truth" and establish a plausible entitlement to relief. *See Iqbal*, 556 U.S. at 680-81. The only allegations that might suggest a defect in the product are those offered to support Plaintiffs' negligence claim. However, those allegations are also conclusory, and lack any apparent connection to the decedent's death. For example, the petition alleges that Mylan's design and manufacture of MTFS were inadequate to avoid "unreasonable, dangerous side-effects" and that Mylan's safety warnings failed to alert users to "potential adverse side effects." *See* Petition [Doc. No. 1-1], ¶ 17.[4] However, the decedent's death is alleged to be caused by a "mixture of drugs and toxicity poisoning." *Id.* ¶ 23. The connection between any side effects suffered by the decedent, which are not stated, and his alleged toxicity poisoning is unclear. Further, the defect argued by Plaintiffs in opposition to dismissal – that Mylan's labeling failed to warn of a danger of combining MTSF with other pain relief drugs – is not alleged in the petition but appears only in Plaintiffs' brief. In short, the Court finds that the petition fails to provide Mylan with fair notice of a plausible claim.

Due to the vagueness of Plaintiffs' allegations, it is difficult, if not impossible, to ascertain the impact of *Mensing* on their claims, even assuming MTSF is the generic equivalent to Duragesic and the holding of *Mensing* applies. For example, Plaintiffs assert that Mylan violated federal regulations regarding post-marketing reports of adverse drug experiences, and they argue in their brief that the Food and Drug Administration (FDA) had recommended new safety warnings. These assertions suggest that Plaintiffs may claim a labeling defect arising from Mylan's failure to obtain

[4] Similarly, the petition merely cites a number of federal regulations allegedly violated. Most of these regulations have no apparent application to MTFS, *see* 21 C.F.R. § 330.10 (regarding over-the-counter drugs); § 369.10 (labeling of drugs for over-the-counter sale); § 201.57 (labeling for prescription drugs described in § 201.56(b)(1)); or no apparent application to the alleged facts of this case, *see id*. § 314.50 (applications for approval of new drugs); § 600.80 (post-marketing reporting of adverse experiences).

permission from the FDA to include additional safety warnings or to update the product label with information from post-marketing reports. Such a claim may be foreclosed by *Mensing*, in which the Supreme Court expressly rejected a similar argument:

> Before the [generic drug manufacturers] could satisfy state law, the FDA – a federal agency – had to undertake special effort permitting them to do so. To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.
>
> Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. The only action the Manufacturers could independently take – asking for the FDA's help – is not a matter of state-law concern. [The plaintiffs'] tort claims are pre-empted.

Mensing, 131 S. Ct. at 2580-81. Accordingly, under the circumstances of this case, the Court finds that Plaintiffs' pleading lacks sufficient factual allegations to provide fair notice of the nature of their claims and that the deficiency is prejudicial to Mylan's ability to answer or otherwise respond. Additional factual allegations should be required before assessing the effect, if any, of *Mensing* on Plaintiffs' case. Thus, at this stage of the proceedings, the Court finds that it need not decide Mylan's request for judicial notice.[5]

Conclusion

For these reasons, the Court concludes that the petition fails to state a claim upon which relief can be granted, but that Plaintiffs should have an opportunity to amend their pleading to supply additional factual allegations to support their asserted theories of recovery.

[5] Should the case reach that point, the Court would expect Mylan to file a motion requesting such relief and to comply with the procedural requirements of Rule 201, rather than simply including the argument in a brief supporting a different motion.

IT IS THEREFORE ORDERED that Mylan's Motion to Dismiss Plaintiffs' Complaint Under Fed. R. Civ. P. 12(b)(6) [Doc. No. 8] is GRANTED, as set forth herein. Plaintiffs shall file an amended complaint within 21 days of the date of this Order.

IT IS SO ORDERED this 28th day of December, 2012.

TIMOTHY D. DEGIUSTI
UNITED STATES DISTRICT JUDGE